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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/811,055 | 03/26/2004 | John B. Cline | 1626-309 | 7598 |

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EXAMINER

BOGART, MICHAEL G

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3761

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|--------------------------------|--|
| Office Action Summary | Application No. 10/811,055 | Applicant(s) CLINE, JOHN B. | |
| | Examiner Michael G. Bogart | Art Unit 3761 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>26 March 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 51 depends on itself. For the purposes of examination, claim 50 is interpreted as depending from claim 50.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 31-58 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,723,079 B2.

Claims 31 and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-114 of U.S. Patent No. 6,689,111 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the presently claimed invention is broader in scope than the corresponding claims of the patented invention. Also, the issued patents claim every limitation of the claimed invention.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31 and 32 are rejected under 35 U.S.C. § 102(b) as being anticipated by Silvanov (US 4,950,223.

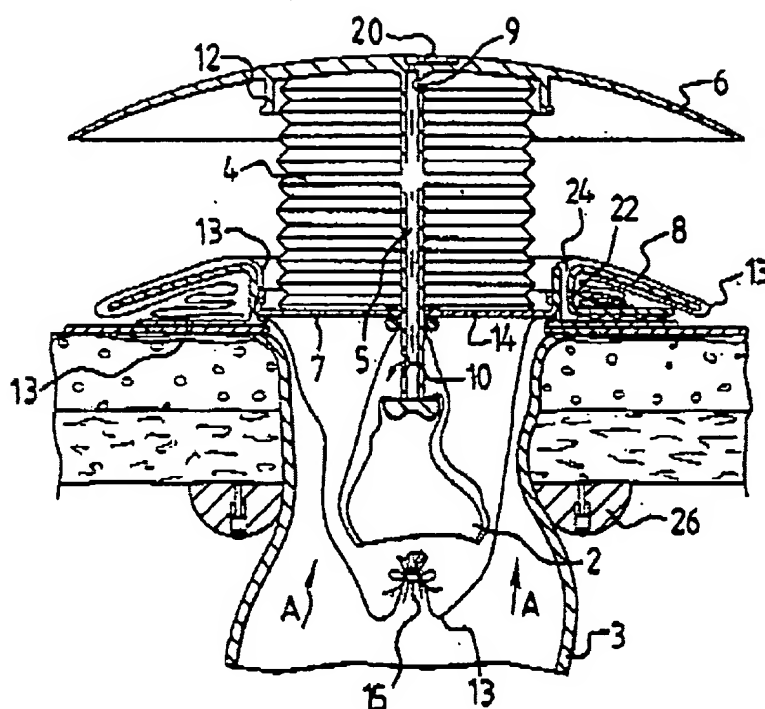


FIG. 1a.

Regarding claim 32, Silvanov teaches a stoma covering means (6, 8) having an edge and wherein said securing means comprises an adhesive layer (35) on said edge (see figure 1f).

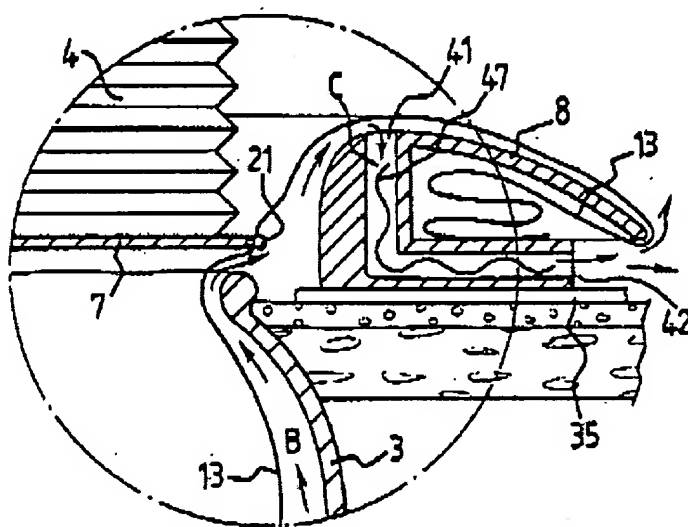
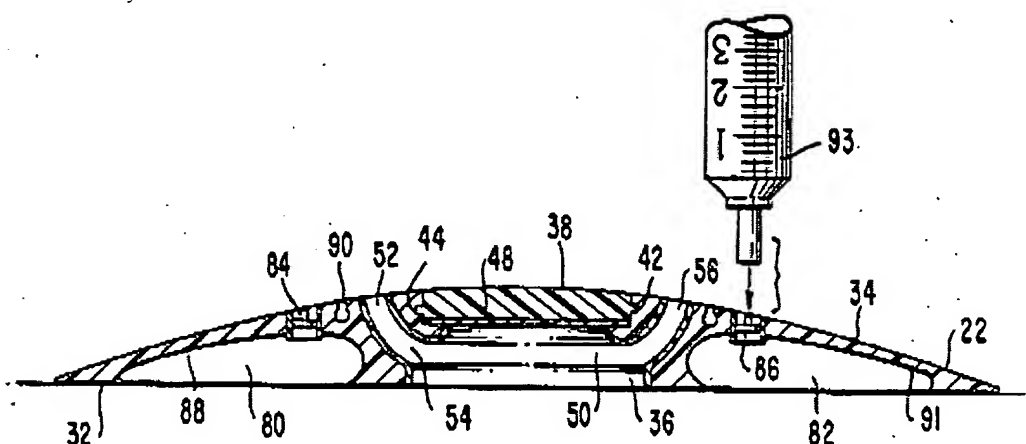


FIG. 1f.

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Claims 31, 33-37, 41, 44, 46, 52 and 53 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kay (4,596,566).

Regarding claim 31, Kay teaches an ostomy device (20) for sealing a stoma, said device (20) comprising means (48), situated externally to the body, for covering the stoma and means (22, 93) for securing said stoma covering means (48) over the stoma to seal the stoma (figure 14).



Regarding claim 33, Kay teaches a securing means (22, 93) comprising a member (22) situated over and sealed to said stoma covering means (32, 48, 50, 78) so as to define a recess (80, 82) that can be pressurized to press said stoma covering means (48, 50) against the stoma.

Regarding claim 34, Silvanov teaches means (93) for pressurizing said recess (80, 82).

Regarding claim 35, Kay teaches an ostomy device (1) for sealing a stoma (3), said device (1) comprising recess defining means (22);

means (93) for securing said recess defining means (22) to the body proximate the stoma;

and

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stoma covering means (48, 50) situated externally to the body, over the stoma within said recess defining means (6, 8), said recess defining means (22) defining with said stoma covering means (48, 50), a recess (80, 82) pressurizable to press said stoma covering means (48, 50) against the stoma.

Regarding claim 36 Kay teaches stoma covering means (48) comprising a flexible membrane (col. 5, lines 1-12). The entire securing means (22, 48) is conformable for wearer comfort.

Regarding claim 37, Kay teaches stoma covering means (48) having an edge and wherein said edge is fixed to the interior of said recess defining means (22)(figure 14).

Regarding claim 38, Kay teaches a means (93) for pressurizing said recess (80, 82).

Regarding claim 41, Kay teaches pressurizing means including pump means (93) integral with said recess defining means (22).

Regarding claim 44, Kay teaches means (84, 86) for limiting the pressure in said recess (80, 82). These one way valves will not let air into the recesses.

Regarding claim 46, Kay teaches use of an external pressurization device (93).

Regarding claims 52, 53, 55, Kay teaches waste collection means (24) comprising a collapsible collection pouch.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

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In the event the examiner is not available, the Examiner's supervisor, Larry Schwartz may be reached at phone number (571) 272-4390. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Bogart
13 June 2005

